U.S. Application No. 09/889,686 Filed: November 28, 2001

REMARKS

Claims 1, 2, 4, 6-8, 10-14, 17, and 18 were pending, all of which have been rejected. Claims 1, 2, 4, 6-8, 10-14, 17, and 18 are cancelled herein. Claims 19-29 are added, and now pending.

Of all presently pending claims, claim 19 is independent. Claim 19 recites a harvested plant being contacted with an inductor in a reaction container via a gas phase surrounding the harvested plant, the gas phase being <u>rapidly</u> displaced by a chemical inductor in its gaseous form. Claim 20 further recites nitrogen, carbon dioxide, ethylene, and ethanol as chemical inductors effecting induction in their gaseous form. Support is found throughout the specification, and particularly on page 7, paragraph. 2 – page 8, paragraph 2; page 9, paragraph 2, lines 6-9; and page 16, paragraph 1, lines 4-6. Claims 21-29 generally correspond to certain of previously pending and now cancelled claims. No new matter is introduced.

Rejections for Indefiniteness under 35 U.S.C. § 112 ¶ 2

The Examiner rejected claim 11 under 35 U.S.C. § 112 ¶ 2 because the recitation of "the induction" is considered lacking antecedent basis. Final Action, page 2, paragraph 6. Applicants have canceled claim 11, and added a corresponding new claim, claim 25. Claim 25 does not recite "the induction." The alleged indefiniteness is thus obviated. Accordingly, Applicants request withdrawal of the rejection under 35 U.S.C. § 112 ¶ 2.

Rejections for Lack of Enablement under 35 U.S.C. § 112 ¶ 1

Claims 1, 2, 4, 6-8, 10-14, 17, and 18 were rejected for allegedly lacking enablement under 35 U.S.C. § 112 ¶ 1. The Examiner stated that the claims were not limited to the gas phase with the exception of claim 2, and that no adequate guidance was provided for the claimed "inducers" or "inducible promoters." Final Action, page 3, paragraph 3 – page 4, paragraph 1.

Applicants cancelled claims 1, 2, 4, 6-8, 10-14, 17, and 18, and added new claims 19-29. Claims 19-29 are drawn to methods for obtaining a protein from a harvested transgenic host plant, which methods require inducing the harvested plant by a chemical inductor via a gas phase. To the extent the Examiner's lack-of-enablement rejection concerns the scope of claims beyond the gas phase, the rejection is obviated.

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Claims 21-23 and 25-27 further recite, in connection with the gas-phase induction, the use of an inducible promoter functionally linked to the gene encoding the protein of interest. Gaseous inductors suitable for use in the method of the present invention are described in the specification, with citations to several scientific publications. Specification, page 7, paragraph 3 – page 8, paragraph 1. Similarly, inducible promoters and the use thereof in connection with chemical inducers as claimed are amply discussed in the specification. Exemplary promoter/inducer pairs are provided. See, e.g., Specification, page 9, paragraph 3 – page 10, paragraph 2. Therefore, neither the claimed inducers nor promoters requires trial-and-error experimentation. Applicants' disclosure fully enables every element of the invention as presently claimed.

Accordingly, Applicants respectfully request that the lack-of-enablement rejection be withdrawn.

Rejections for Anticipation under 35 U.S.C. § 102(e)

Claims 1, 2, 4, 6-8, 10, 17, and 18 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,194,201 (hereafter "the '201 patent"). Final Action, page 4, paragraph 2 – page 6, paragraph 1.

Claims 1, 2, 4, 6-8, 10, 17, and 18 are being cancelled herein and new claims 19-29 added.

Claim 19 recites a harvested plant being contacted with an inductor in a reaction container via a gas phase surrounding the harvested plant, the gas phase being <u>rapidly</u> displaced by a chemical inductor in its gaseous form. Because the '201 patent does not teach the reaction container as claimed, nor the rapid displacement of the gas phase, it cannot anticipate claim 19.

For example, unlike the method of Applicants' invention which includes a rapid displacement of the gas phase (specification, page 16, paragraph 1), the gas phase in the Anaerocult System of the '201 patent, i.e. oxygen, is displaced over several hours. Such slow displacement is consistent with the teachings of other prior art that only the <u>gradual</u> but not rapid displacement of oxygen leads to a hypoxic acclimation necessary for metabolism giving rise to the production of proteins. See, e.g., *German et al.*, page 168, left column, paragraph 1; page 169, right column; page 171, left column, paragraph 1; and page 173, right column, paragraph 2. Thus, there is no suggestion in prior art teachings for rapid displacement of the gas phase.

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Rather, the prior art including the '201 patent teaches away from rapid displacement of the gas phase.

Further, Applicants respectfully submit that the Examiner erred in considering column 4, lines 31-36 of the '201 patent as the alleged evidence for a post harvest production system in sliced potato tubes. That experiment investigates enhanced resistance against the bacterial pathogen *Erwinia carotovara* for potato tubers bearing the chimeric *pGapC4-T4lys* gene; it does not describe an anaerobic post-harvest production system as presently claimed. No air-tight condition was applied as the boxes used for incubation are intentionally maintained under normal air. No deoxidizing of the gas phase surrounding the tuber was carried out. No T2lys protein was detected (only biological function of the potato was assayed), nor isolation made in that experiment. Moreover, it should be noted that "comminution of the plant tissue is not necessary" by the harvesting according to the present invention. Specification, page 2, paragraph 3. Slicing in the '201 patent is only a prerequisite for the phytopathological test, it is not part of any post-harvest production technology, certainly not what Applicants teach and claim in the instant application.

Therefore, failing to disclose every element of the claimed invention, the '201 patent cannot anticipate claim 19. For at least the same reasons, the '201 patent cannot anticipate claim 20-29, which depend from claim 19.

Applicants respectfully request that this rejection be withdrawn.

Rejections for Anticipation under 35 U.S.C. § 102(b)

Claims 1, 2, 4, 6-8, 10, 17, and 18 have been rejected under 35 U.S.C. § 102(b) as being anticipated by *Kohler et al.*, 1996, "A promoter for strong and ubiquitous anaerobic gene expression in tobacco," The Plant Journal, vol. 10, pages 175-183 (hereafter "*Kohler et al.*"). Final Action, page 6, paragraphs 3-5.

Claims 1, 2, 4, 6-8, 10-14, 17, and 18 are being cancelled herein and new claims 19-29 added.

Claim 19 recites a harvested plant being contacted with an inductor in a reaction container via a gas phase surrounding the harvested plant, the gas phase being <u>rapidly</u> displaced by a chemical inductor in its gaseous form. Like the '201 patent, *Kohler et al.* does not disclose the reaction container as claimed, nor the rapid displacement of the gas phase. Further, there is

no disclosure nor suggestion of a post-harvest production system in *Kohler et al.* as Applicants teach and claim in the instant application.

To clarify based on Applicants' disclosure, the term "post-harvest production" refers to induction of expression of foreign proteins after harvest, and the term "harvest" refers to removal of the plant or parts of the plant from its previous growing environment. According to Applicants' invention, post-harvest production is not harvesting of plant materials which contains expressed foreign proteins for homogenization of the plant materials and isolation of the proteins. Kohler et al. does not describe any post-harvest expression of foreign proteins; rather, it describes the use of intact seedlings (small plantlets grown from seeks) which are maintained intact on agar plates in Petri dishes throughout all experiments. The complete Petri dishes are subjected to different gas phases without effecting the seedlings. No disclosure or suggestion is offered in Kohler et al. that those experiments would work with harvested (cut) seedlings as well.

Kohler et al. fails to disclose each and every element of claim 19, and therefore cannot anticipate claim 19. For at least the same reasons, Kohler et al. cannot anticipate claims 20-29, which depend from claim 19.

Withdrawal of this rejection is respectfully requested.

Rejections for Obviousness under 35 U.S.C. § 103

Claims 1, 2, 4, 6-8, 10-14, 17, and 18 have been rejected under 35 U.S.C. § 103(a) as being obvious and thus unpatentable over *Kohler et al.* in view of WO 95/00555. Final Action, page 6, paragraph 6 – page 7, paragraph 1.

Claims 1, 2, 4, 6-8, 10-14, 17, and 18 are being cancelled herein and new claims 19-29 added.

The Examiner asserted that *Kohler et al.* describes post-harvest production and that WO 95/00555 describes the recombinase LBD system. Final Action, page 7, paragraph 1. For the reasons set forth above, *Kohler et al.* does not describes post-harvest production nor the rapid displacement of the gas phase as presently claimed by Applicants. Therefore, *Kohler et al.* alone, or in combination with WO 95/00555, does not render obvious claim 19 or any of its dependent claims.

Applicants respectfully request that the obviousness rejection be withdrawn.

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Applicants solicit an office action indicating allowability of the pending claims. The Examiner is invited to telephone the undersigned if further discussion should facilitate moving this application to allowance.

Respectfully submitted,

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